

What is claimed is:

CLAIMS

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1. A composition comprising minoxidil, a non-carbomeric thickening agent, and a pharmaceutically acceptable solvent, wherein said minoxidil is substantially solubilized in said composition.
  2. A composition of claim 1, wherein said composition is in the form of a gel.
  3. A composition of claim 1 which comprises from greater than about 0.01% to about 8% minoxidil.
  - 10 Sub E' Cent 4. A composition of claim 3 which comprises from greater than about 3% to about 8% minoxidil.
  5. A composition of claim 4 which comprises from about 5% to about 6% minoxidil.
  6. A composition of claim 5 which comprises about 5% minoxidil.
  - 15 7. A composition of claim 1, wherein said pharmaceutically acceptable solvent is selected from the group consisting of alcohols and polyols.
  8. A composition of claim 7, wherein said solvent comprises an alcohol.
  9. A composition of claim 8, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.
  - 20 10. A composition of claim 9, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.

11. A composition of claim 7, wherein said solvent comprises a polyol.

12. A composition of claim 11, wherein said polyol comprises a glycol.

13. A composition of claim 12, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

14. A composition of claim 13, wherein said glycol is propylene glycol.

15. A composition of claim 7, wherein said solvent comprises a mixture of an alcohol and a glycol.

16. A composition of claim 15, wherein said solvent comprises a mixture of ethanol and propylene glycol.

17. A composition of claim 1, further comprising a neutralizing agent.

18. A composition of claim 17, wherein said neutralizing agent is selected from the group consisting of ammonium hydroxide, arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, aminomethyl propanol, sodium hydroxide, and potassium hydroxide.

19. A composition of claim 18, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

20. A composition of claim 19, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

21. A composition of claim 1, wherein said solvent is present in said composition in an amount of at least about 20%.

22. A composition of claim 21 which comprises from about 20% to about 99% solvent.

23. A composition of claim 1, further comprising pharmaceutically acceptable additives and ingredients selected from the group consisting of hair conditioners, panthenol derivatives, calcium pantothenate, colorants, fragrances, fragrance modifiers, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, oils, emulsifiers, wetting agents, sunscreens, and anti-irritants.

24. A composition of claim 1, wherein said non-carbomeric thickening agent is selected from the group consisting of organic thickening agents and inorganic thickening agents.

25. A composition of claim 24, wherein said non-carbomeric thickening agent comprises an organic thickening agent which is a polymer.

26. A composition of claim 25, wherein said polymer is selected from the group consisting of starches, gums, pectin, casein, gelatin, phycocolloids, and synthetic polymers.

27. A composition of claim 26, wherein said polymer is selected from the group consisting of alginates and salts and derivatives thereof, acacia, carrageenan, guar gum, karaya gum, locust bean gum, tragacanth, xanthan gum, carboxymethylcellulose and salts thereof, ethylcellulose, hydroxyethylcellulose, methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose, hyaluronic acid and salts thereof, and polydextrose.

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5 28. A composition of claim 27, wherein said polymer is selected from the group consisting of crosslinked copolymers of acrylic acid, dimethicone copolyols, acrylic/acrylate copolymers, polyacrylamide, ethylene/sodium acrylate copolymer, acrylamide/sodium acrylate copolymer, sodium acrylate/vinyl alcohol copolymer, sodium polymethacrylate, sodium polystyrene sulfonate, povidone and derivatives thereof, polyquaternium compounds, polyvinyl alcohol, polyethylene oxide, and poloxamers.

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10 29. A composition of claim 28, wherein said polymer comprises a crosslinked copolymer of acrylic acid.

30. A composition of claim 29, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C<sub>10-30</sub> alkyl acrylate crosspolymer.

31. A composition of claim 24, wherein said thickening agent comprises an inorganic thickening agent.

15 32. A composition of claim 31, wherein said inorganic thickening agent is selected from the group consisting of bentonite, magnesium aluminum silicate, and colloidal silicon dioxide.

33. A composition of claim 2, wherein said thickening agent comprises a crosslinked copolymer of acrylic acid.

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20 34. A composition of claim 33, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C<sub>10-30</sub> alkyl acrylate crosspolymer.

35. A composition of claim 33 wherein said solvent is present in said composition in an amount of at least about 20%.

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36. A composition comprising greater than 3% minoxidil, a pharmaceutically acceptable solvent, and a solvent-tolerant carbomer, wherein said minoxidil is substantially solubilized in said composition.

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37. A composition of claim 36 which is in the form of a gel.

38. A composition of claim 36 which comprises from greater than 3% to about 8% minoxidil.

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39. A composition of claim 38 which comprises from about 4% to about 7% minoxidil.

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40. A composition of claim 39 which comprises from about 5% to about 6% minoxidil.

41. A composition of claim 40 which comprises about 5% minoxidil.

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42. A composition of claim 37 wherein said pharmaceutically acceptable solvent is selected from the group consisting of alcohols and polyols.

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43. A composition of claim 42, wherein said solvent comprises an alcohol.

44. A composition of claim 43, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.

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45. A composition of claim 44, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.

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46. A composition of claim 42, wherein said solvent comprises a polyol.

47. A composition of claim 46, wherein said polyol comprises a glycol.

48. A composition of claim 47, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

49. A composition of claim 48, wherein said glycol is propylene glycol.

50. A composition of claim 49, wherein said solvent comprises a mixture of an alcohol and a glycol.

51. A composition of claim 50, wherein said solvent comprises a mixture of ethanol and propylene glycol.

52. A composition of claim 37, further comprising a neutralizing agent.

53. A composition of claim 52, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.

54. A composition of claim 53, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

55. A composition of claim 54, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

Sub a<sup>8</sup> 56. A composition of claim 37, wherein said solvent is present in said composition in an amount of at least about 20%.

57. A composition of claim 56 which comprises from about 20% to about 99% solvent.

58. A composition of claim 57 wherein the ratio of solvent to minoxidil is about 10:1.

59. A composition of claim 58 wherein the ratio of solvent to minoxidil is about 12:1.

60. A composition of claim 59 wherein the ratio of solvent to minoxidil is about 15:1.

61. A composition of claim 37, further comprising pharmaceutically acceptable additives and ingredients selected from the group consisting of hair conditioners, panthenol derivatives, calcium pantothenate, colorants, fragrances, fragrance modifiers, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, oils, emulsifiers, wetting agents, sunscreens, and anti-irritants.

62. A composition comprising:  
from greater than about 3% to about 8% of minoxidil;  
from about 30% to about 80% of a polyol;  
from about 10% to about 50% of an alcohol;  
from about 0.01% to about 50% of a non-carbomeric polymer;  
from about 0% to about 3% of a neutralizing agent; and  
water (qs); wherein said minoxidil is substantially solubilized in said composition.

63. A composition of claim 62 which is in the form of a gel.

64. A composition of claim 62, wherein said polyol comprises a glycol.

65. A composition of claim 64, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

66. A composition of claim 65, wherein said glycol is propylene glycol.

67. A composition of claim 62, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.

68. A composition of claim 67, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.

69. A composition of claim 62, wherein said non-carbomeric thickening agent comprises a crosslinked copolymer of acrylic acid.

70. A composition of claim 69 wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C<sub>10-30</sub> alkyl acrylate crosspolymer.

71. A composition of claim 62, wherein said neutralizing agent is selected from the group consisting of arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, and aminomethyl propanol.



72. A composition of claim 71, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypopyl ethylenediamine, and mixtures thereof.

5 73. A composition of claim 72, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

74. A composition of claim 62, comprising:  
from about 4% to about 7% of minoxidil;  
from about 40% to about 70% of a polyol;  
from about 20% to about 30% of an alcohol;  
from about 0.05% to about 3% of a non-carbomeric polymer; and  
from about 0.03% to about 1% of a neutralizing agent.

15 75. A composition of claim 74, comprising:  
from about 5% to about 6% of minoxidil;  
from about 50% to about 60% of a polyol; and  
from about 25% to about 30% of an alcohol.

20 76. A composition of claim 74 comprising:  
about 5% of minoxidil;  
about 53% of a polyol;  
about 26% of an alcohol;  
from about 0.25% to about 1% of a non-carbomeric polymer; and  
from about 0.15% to about 0.6% of a neutralizing agent.

25 77. A composition of claim 62, wherein said non-carbomeric polymer is selected from the group consisting of alginates and salts and derivatives thereof, acacia, carrageenan, guar gum, karaya gum, locust bean gum, tragacanth, xanthan gum, carboxymethylcellulose and salts thereof, ethylcellulose, hydroxyethylcellulose, methylcellulose,

78. A composition of claim 62, wherein said non-carbomeric polymer is selected from the group consisting of crosslinked copolymers of acrylic acid, dimethicone copolyols, acrylic/acrylate copolymers, polyacrylamide, ethylene/sodium acrylate copolymer, acrylamide/sodium acrylate copolymer, sodium acrylate/vinyl alcohol copolymer, sodium polymethacrylate, sodium polystyrene sulfonate, povidone and derivatives thereof, polyquaternium compounds, polyvinyl alcohol, polyethylene oxide, and poloxamers.

80. A composition of claim 79 which comprises from about 0.01 to about 8% minoxidil.

81. A composition of claim 79, wherein said thickening agent is selected from the group consisting of organic thickening agents and inorganic thickening agents.

82. A composition of claim 81, wherein said thickening agent comprises an organic thickening agent which is a polymer.

83. A composition of claim 82, wherein said polymeric thickening agent is selected from the group consisting of starches, gums, pectin, casein, gelatin, phycocolloids and synthetic polymers.

84. A composition of claim 83, wherein said polymeric thickening agent is selected from the group consisting of alginates and salts and derivatives thereof, acacia, carrageenan, guar gum, karaya gum, locust bean gum, tragacanth, xanthan gum, carboxymethylcellulose and salts thereof, ethylcellulose, hydroxyethylcellulose, methylcellulose,

hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose, hyaluronic acid and salts thereof, and polydextrose.

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85. A composition of claim 83, wherein said polymeric thickening agent is selected from the group consisting of crosslinked homopolymers of acrylic acid, crosslinked copolymers of acrylic acid, crosslinked interpolymers of acrylic acids, dimethicone copolyols, acrylic/acrylate copolymers, polyacrylamide, ethylene/sodium acrylate copolymer, acrylamide/sodium acrylate copolymer, sodium acrylate/vinyl alcohol copolymer, sodium polymethacrylate, sodium polystyrene sulfonate, powidone and derivatives thereof, polyquaternium compounds, polyvinyl alcohol, polyethylene oxide, and poloxamers.

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86. A composition of claim 85, wherein said polymeric thickening agent comprises a crosslinked copolymer of acrylic acid.

87. A composition of claim 86, wherein said crosslinked copolymer of acrylic acid comprises an acrylate/C<sub>10-30</sub> alkyl acrylate crosspolymer.

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88. A composition of claim 81, wherein said thickening agent comprises an inorganic thickening agent.

89. A composition of claim 88, wherein said inorganic thickening agent is selected from the group consisting of bentonite, magnesium aluminum silicate, and colloidal silicon dioxide.

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90. A composition of claim 79, wherein said pharmaceutically acceptable solvent is selected from the group consisting of an alcohol and a polyol.

91. A composition of claim 90, wherein said solvent comprises an alcohol.

92. A composition of claim 91, wherein said alcohol is selected from the group consisting of ethanol, propanol, and butanol.

93. A composition of claim 92, wherein said alcohol is selected from the group consisting of ethanol and isopropanol.

94. A composition of claim 90, wherein said solvent comprises a polyol.

95. A composition of claim 94, wherein said polyol comprises a glycol.

5 96. A composition of claim 95, wherein said glycol is selected from the group consisting of propylene glycol, dipropylene glycol, hexylene glycol, 1,3-butylene glycol, PEG-200, PEG-400, and glycerol.

97. A composition of claim 96, wherein said glycol is propylene glycol.

98. A composition of claim 79, further comprising a neutralizing agent.

99. A composition of claim 98, wherein said neutralizing agent is selected from the group consisting of ammonium hydroxide, arginine, 2-amino-2-methyl-1-propanol, dimethanolamine, dibutanolamine, diisobutanolamine, tributanolamine, triisobutanolamine, tri-sec-butanolamine, tripropylamine, ethanolamine, diethanolamine, triethanolamine, PEG-15 cocamine, diisopropanolamine, methylethanolamine, diisopropylamine, dipropylenetriamine, tromethamine, isopropylamine ethylene diamine, triisopropanolamine, tetrahydroxypropyl ethylenediamine, trimethamine, 2-aminobutanol, aminoethyl propanediol, aminomethyl propanediol, aminomethyl propanol, sodium hydroxide, and potassium hydroxide.

15 100. A composition of claim 99, wherein said neutralizing agent is selected from the group consisting of 2-amino-2-methyl-1-propanol, diisopropanolamine, triisopropanolamine, and tetrahydroxypropyl ethylenediamine.

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101. A composition of claim 100, wherein said neutralizing agent is 2-amino-2-methyl-1-propanol.

102. A composition of claim 79, wherein said solvent is present in said composition in an amount of at least about 20%.

103. A composition of claim 102 which comprises from about 20% to about 99% solvent.

104. A composition of claim 79, further comprising pharmaceutically acceptable additives and ingredients selected from the group consisting of hair conditioners, panthenol derivatives, calcium pantothenate, colorants, fragrances, fragrance modifiers, vitamin E, penetration modifiers, surfactants, cosmetic agents, fatty acids and fatty acid esters, herbal extracts, henna, oils, emulsifiers, wetting agents, sunscreens, and anti-irritants.

105. A process for preparing a composition comprising:  
from greater than about 3% to about 8% of minoxidil;  
from about 30% to about 80% of a polyol;  
from about 10% to about 50% of an alcohol;  
from about 0.01% to about 3% of a non-carbomeric polymer;  
from about 0% to about 3% of a neutralizing agent; and  
water (qs); wherein said minoxidil is substantially solubilized in said composition, said process comprising:

- (a) providing a solution comprising said minoxidil, said polyol, a portion of said alcohol and a substantial majority of said neutralizing agent;
- (b) providing a dispersion comprising said polymeric thickening agent, the remaining portion of said alcohol, any remainder of said neutralizing agent and said water; and
- (c) combining said solution and said dispersion to provide said composition.

106. A process according to claim 105, wherein said portion of said alcohol comprises about 50% of said alcohol.

107. A process according to claim 105 comprising mixing together said minoxidil, said polyol, said alcohol and said neutralizing agent to provide said solution.

108. A process according to claim 107, wherein said mixing is conducted at about room temperature.

5 109. A process according to claim 105, wherein said neutralizing agent is substantially completely added to said solution.

10 110. A process for preparing a non-gelled composition comprising minoxidil, a thickening agent, a pharmaceutically acceptable solvent, and water, wherein said minoxidil is substantially solubilized in said non-gelled composition, said process comprising combining together said minoxidil, thickening agent, pharmaceutically acceptable solvent and water to provide said composition.

111. A method for treating or preventing hair loss in a region of a patient, said method comprising topically administering to said region a composition according to claim 1.

112. A method according to claim 111, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

113. A method for treating or preventing hair loss in a region of a patient, said method comprising topically administering to said region a composition according to claim 37.

114. A method according to claim 113, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

115. A method for treating or preventing hair loss in a region of a patient, said method comprising topically administering to said region a composition according to claim 62.

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116. A method according to claim 115, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

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117. A method for treating or preventing hair loss in a region of a patient, said method comprising topically administering to said region a composition according to claim 79.

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118. A method according to claim 117, wherein said hair loss comprises androgenetic alopecia, frontal hair loss, bitemporal recession, vertex balding, mid-anterior balding, alopecia areata, anagen hair loss, diffuse alopecia, and telogen effluvium.

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